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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,899	06/27/2003	Lisa M. Donnelly	022956-0218	7787
21125	7590	11/15/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,899	DONNELLY ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' cancellation of claims 10, 18, and 19 in the reply filed on September 2, 2005 is acknowledged.
2. Applicants' amendment of claims 1, 2, 5, and 17 in the reply filed on September 2, 2005 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-9, 11, 12, and 14-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hays et al. (US 2002/0072797 A1).

Referring to Figures 24-28, Hays et al. disclose a graft fixation device for fixing a graft member within a bone tunnel (bone tunnel 600), the device comprising: (i) a bioabsorbable (see paragraphs 0091-0092 for a list of bioabsorbable materials) radially expandable sheath (sheath 400) having a substantially closed distal end (e.g., distal tip 409: "substantially closed" is broadly interpreted) with at least two sidewalls (sidewalls 405) extending proximally therefrom and defining a central lumen (central lumen 450), each sidewall having a substantially concave outer surface (concave surfaces 410-440) *adapted to seat* (emphasis added to functional language) a graft member (see entire document), and each sidewall being at least partially separated by a

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longitudinally oriented slot (longitudinally extending fracture regions 490, which may include cut-out areas 406, 452, and/or longitudinal flexion regions 480: see paragraphs 0084 and 0086-0089) extending from a proximal end along a substantial length of each sidewall and terminating at a position proximal to the distal end (see Figures 24-28; see paragraphs 0084 and 0086-0089).

With regards to the sheath expander and the functional language associated to it, see threaded sheath expander 700, and the entire document. With regards to claims 4 and 14, see ribs 402.

With regards to claims 5 and 15, see tabs 1000. With regards to claims 6, 7, 16, and 17, see threaded sheath expander 700, and paragraphs 0082-0090. With regards to claims 8 and 9, see paragraphs 0091-0092. Paragraph 0090 teach the use of a wide variety of sheath expanders and a kit.

Response to Arguments

5. Applicant's arguments filed September 2, 2005 have been fully considered but they are not persuasive.

Applicants argue that Hays et al. (US 2002/0072797 A1) “does not teach or even suggest slots that separate the sidewalls and that extend from a proximal end and terminate just proximal to a distal end”. Applicants also argue that Hays et al. “weakened fracture regions are not slots that separate the sidewalls” and “the thinned material or groove formed between the sidewalls cannot be considered to be a slot that separates the sidewalls”. The Examiner respectfully disagrees.

Contrary to Applicants' argument, Hays et al. does teach a “longitudinally oriented slot”. The term “slot” is generally defined as: “*a narrow opening; a groove or slit; a narrow opening*”

or groove". Hays et al. clearly disclose region 490 and region 480 either as a weakened fracture, or, as a longitudinal groove (see paragraphs 0084 and 0086). Furthermore, Hays et al. disclose that said longitudinal groove may extend "substantially along or entirely along the length of sidewall 401" (see paragraphs 0084 and 0086). The position at which the longitudinal slot terminates may be proximal to the distal end (see Figures 24-28) since, based on the above-mentioned teachings recited in Hays et al., an area or region (i.e., distal end) will provide structural integrity to radially expandable sheath 400 so sidewalls 405 will not separate from one another during expansion of said expandable sheath. Also, the Examiner posits that the particular locality of said area or region could vary (i.e., design choice) as long as there are longitudinal slots with a length sufficient enough to allow undisturbed expansion of said radially expandable sheath while at the same time maintaining structural integrity of said expandable sheath (see paragraphs 0082-0092, particularly paragraphs 0089 and 0091).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Hays et al. (US 2002/0072797 A1).

Hays et al. disclose the invention as claimed (see 102(b) rejection above). Although Hays et al. disclose tapering distal tip, they did not disclose expressly said distal tip as being bullet-

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shaped. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have modified Hays et al.'s distal tip 409 to have a bullet (rounded) shape because Applicants have not disclosed that shaping a distal tip to have a bullet (rounded) shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well with either a tapered distal end or a bullet-shaped distal end because both shapes would have permitted the radially expandable sheath to be easily inserted into a bone tunnel.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hays et al. (US 2002/0072797 A1) in view of Simonian et al. (US 6,099,530).

Hays et al. disclose the invention as claimed (see 102(b) rejection above). Although Hays et al. disclose a central lumen, they did not particularly disclose said lumen as receiving a guide wire. However, this is well known in the art. For example, Simonian et al. disclose a radially expandable sheath comprising a lumen (cannulation 138) for receiving a guide wire in order to facilitate implantation of the device (see column 4, lines 27-37). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of a radially expandable sheath comprising a lumen for receiving a guide wire, as taught by Simonian et al., with the radially expandable sheath of Hays et al., in order to facilitate implantation of the device.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



November 7, 2005



David H. Willse
Primary Examiner